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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,257	06/12/2001	Sachiko Yamamoto	70281/55,986	4822

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BOSTON, MA 02209

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant(s)

09/879,257

Applicant(s)

YAMAMOTO ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 19-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-16, 19 and 47 is/are rejected.
- 7) ☒ Claim(s) 48-51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Claims 14-16, 19, 47-51 are under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-16, 19, and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed April 29, 2003 (Paper No. 12) have been fully considered but they are not persuasive. The Examiner respectfully disagrees with Applicants' position that there is sufficient description to show one of ordinary skill in the art that the inventors had possession of the claimed hybrid enzymes for reasons of record and for the reasons stated below.

The claims are directed to any hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at any position of the amino acid sequence of any glucose-6-phosphate dehydrogenase (G6PDH) of any amino acid sequence, wherein when said peptide binds to any material having binding ability to the peptide the activity of any glucose-6-phosphate dehydrogenase is then modulated.

While the specification provides a written description for following representative species encompassed by these claims in Table 2, specifically, modified G6PDH enzymes designated as Asp294/Ser295, Leu305/Asp306, Asp306/Val307, Pro308/Ala309, Ala309/Asp310, Glu362/Gln363, and C-and N-terminal, in which a peptide of amino acid sequence SEQ ID NOS: 1-5, 46, or 50 are inserted at the designated position of a G6PDH enzyme consisting of the amino acid sequence of SEQ ID NO: 6, there is no written description for the any hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at the reacted position in which the resulting hybrid protein can have any activity or biological function.

Thus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in

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possession of the claimed invention.

4. Claims 14-16, 19, and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified G6PDH enzymes listed in Table 2 of the specification, specifically, modified G6PDH enzymes designated as Asp294/Ser295, Leu305/Asp306, Asp306/Val307, Pro308/Ala309, Ala309/Asp310, Glu362/Gln363, and C- and N-terminal, in which a peptide of amino acid sequence SEQ ID NOs:1-5, 46, or 50 is inserted at the designated position of a G6PDH enzyme consisting of the amino acid sequence of SEQ ID NO: 6; does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed April 29, 2003 (Paper No. 12) have been fully considered but they are not persuasive. The Examiner respectfully disagrees with Applicants' position that the specification provides enough guidance to enable one of ordinary skill in the art to practice the invention for reasons of record and for the reasons stated below.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed invention is enormous and entails obtaining G6PD of amino acid sequence SEQ ID NO: 6 and any peptide of any amino acid sequence from any biological source, inserting the peptide in the recited position, and then determining whether G6PDH activity is modulated when said peptide binds to any material having binding ability to the peptide. Since routine experimentation in the art does not include such experimentation where the expectation of obtaining the specific amino acid sequence of the claimed peptides and the resulting hybrid enzyme/protein of the invention is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and amino acid sequence of the claimed hybrid enzyme. Without such a guidance, the experimentation left to those skilled in the art is undue.

### *Conclusion*

5. No claim is allowed.

6. Claims 48-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this

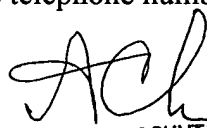
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Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

  
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